

**UNITED STATES COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT**

**2013-1206**

**EXELA PHARMA SCIENCES, LLC, EXELA PHARMSCI, INC., and  
EXELA HOLDINGS, INC.**

*Plaintiffs-Appellants,*

**v.**

**TERESA STANEK REA, DIRECTOR,  
UNITED STATES PATENT AND TRADEMARK OFFICE,**

*Defendant-Appellee,*

**and**

**CADENCE PHARMACEUTICALS, INC., and SCR PHARMATOP,**

*Intervenors.*

Appeal from United States District Court for the Eastern District of Virginia in  
Case No. 12-CV-0469, Judge Liam O'Grady

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**APPEAL BRIEF OF DEFENDANT-APPELLEE  
TERESA STANEK REA, ACTING DIRECTOR,  
UNITED STATES PATENT & TRADEMARK OFFICE**

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NATHAN KELLEY  
Acting Solicitor

SYDNEY JOHNSON  
JAMIE SIMPSON  
Associate Solicitors  
United States Patent and  
Trademark Office

DANA J. BOENTE  
Acting United States Attorney

DENNIS C. BARGHAAN, JR.  
Assistant U.S. Attorney  
2100 Jamieson Avenue  
Alexandria, Virginia 22314  
(703) 299-3891

# TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES .....	iii
STATEMENT OF RELATED CASES .....	1
STATEMENT OF JURISDICTION.....	1
STATEMENT OF THE ISSUES.....	2
STATEMENT OF THE CASE.....	2
STATEMENT OF THE FACTS .....	4
1.    Revival of Abandoned Patent Applications .....	4
2.    USPTO’s 2003 Revival of PCT/FR01/01749 .....	7
3.    Delaware Patent Infringement Litigation Against Exela .....	8
4.    Exela’s Attempts to Avoid Infringement Liability By Challenging the USPTO’s 2003 Revival.....	9
5.    The District Court’s Decisions .....	11
SUMMARY OF THE ARGUMENT .....	14
ARGUMENT .....	16
I.    STANDARD OF REVIEW .....	16
II.   EXELA’S CLAIMS ARE TIME-BARRED UNDER CONTROLLING REGIONAL CIRCUIT AUTHORITY.....	16

A.	As Exela Conceded Below, the Fourth Circuit’s Statute of Limitations Jurisprudence Governs this Court’s Analysis .....	17
B.	The Fourth Circuit’s <i>Hire Order</i> Decision Mandated Dismissal of Exela’s APA Claims.....	19
C.	Exela’s Perfunctory and Unsanctioned 2011 Request for Reconsideration Did Not Restart the § 2401 “Clock” .....	30
III.	CONGRESS PRECLUDED THIRD-PARTIES FROM ATTEMPTING TO AVOID INFRINGEMENT LIABILITY THROUGH JUDICIAL REVIEW OF USPTO REVIVAL DECISIONS .....	35
A.	This Court in <i>Aristocrat</i> Held that Congress Did Not Intend For A Putative Third-Party Infringer to Shield Itself From Infringement Liability by Challenging the USPTO’s Revival Decisions .....	36
B.	The <i>Ex Parte</i> Nature of USPTO Revival Proceedings Under the Patent Act Provides Further Evidence of Congressional Intent to Preclude APA Review .....	42
	CONCLUSION .....	47
	CERTIFICATE OF SERVICE .....	48
	CERTIFICATE OF COMPLIANCE .....	49

## TABLE OF AUTHORITIES

Page

### CASES

<i>Am. Air Par. For. Co. v. United States</i> , 718 F.2d 1546 (Fed. Cir. 1983) .....	42
<i>Am. Bioscience, Inc. v. Thompson</i> , 269 F.3d 1077 (D.C. Cir. 2001).....	8
<i>Am. Canoe Ass’n v. Murphy Farms, Inc.</i> , 326 F.3d 505 (4 <sup>th</sup> Cir. 2003) .....	13
<i>Animal Legal Defense Fund v. Quigg</i> , 932 F.2d 920 (Fed. Cir. 1991) .....	39, 41
<i>Aristocrat Techs. Australia Pty. Ltd. v. Int’l Game Tech.</i> , 543 F.3d 657 (Fed. Cir. 2008) .....	passim
<i>Ashcroft v. Iqbal</i> , 556 U.S. 662 (2009).....	31
<i>Barlow v. Collins</i> , 397 U.S. 159 (1970).....	36
<i>Bay Area Laundry &amp; Dry Cleaning Pension Trust Fund v. Ferbar Corp. of California, Inc.</i> , 522 U.S. 192 (1997).....	22, 23
<i>Block v. Comm. Nut. Inst.</i> , 467 U.S. 340 (1984).....	passim
<i>Block v. North Dakota</i> , 461 U.S. 273 (1983).....	42
<i>Bowen v. Mich. Acad. of Family Physicians</i> , 476 U.S. 667 (1986).....	46

<i>Bray v. United States</i> , 785 F.2d 989 (Fed. Cir. 1986) .....	18
<i>Brown v. GSA</i> , 425 U.S. 820 (1976).....	42
<i>Burandt v. Dudas</i> , 528 F.3d 1329 (Fed. Cir. 2008) .....	46
<i>Crown Coat Front Co. v. United States</i> , 386 U.S. 503 (1967).....	22, 24
<i>Ctr. for Biol. Diversity v. Hamilton</i> , 453 F.3d 1331 (11 <sup>th</sup> Cir. 2006) .....	20
<i>Dunn-McCampbell Royalty Interest, Inc. v. NPS</i> , 112 F.3d 1283 (5 <sup>th</sup> Cir. 1987) .....	S29
<i>Ex Parte McCardle</i> , 74 U.S. (7 Wall.) 506 (1868) .....	6
<i>Functional Music, Inc. v. FCC</i> , 274 F.2d 543 (D.C. Cir. 1958).....	29
<i>Hallmark Cards v. Lehman</i> , 959 F. Supp. 539 (D.D.C. 1997).....	45, 46
<i>Hardin v. Jackson</i> , 625 F.3d 739 (D.C. Cir. 2010).....	20
<i>Harris v. FAA</i> , 353 F.3d 1006 (D.C. Cir. 2004).....	19
<i>Hewlett-Packard Co. v. Acceleron LLC</i> , 587 F.3d 1358 (Fed. Cir. 2009) .....	16
<i>Hire Order, Ltd. v. Marianos</i> , 698 F.3d 168 (4 <sup>th</sup> Cir. 2012) .....	passim

<i>Hitachi Metals, Ltd. v. Quigg</i> , 776 F. Supp. 3 (D.D.C. 1991).....	43
<i>ICC v. Brotherhood of Locomotive Engineers</i> , 482 U.S. 270 (1987).....	14, 32, 34
<i>Jersey Heights Neighborhood Ass’n v. Glendenning</i> , 174 F.3d 180 (4 <sup>th</sup> Cir. 1999) .....	19, 22, 28
<i>Landmark Screens, LLC v. Morgan, Lewis &amp; Bockius, LLP</i> , 676 F.3d 1354 (Fed. Cir. 2012) .....	17, 18
<i>Magnola Metallurgy, Inc. v. United States</i> , 508 F.3d 1349 (Fed. Cir. 2007) .....	34
<i>McCauley v. Home Loan Inv. Bank, F.S.B.</i> , 710 F.3d 551 (4 <sup>th</sup> Cir. 2013) .....	16
<i>Nat’l Mining Ass’n v. U.S. Dep’t of Interior</i> , 70 F.3d 1345 (D.C. Cir. 1995).....	32
<i>NLRB Union v. FLRA</i> , 834 F.2d 191 (D.C. Cir. 1987).....	25
<i>P &amp; V Enters. v. U.S. Army Corps of Eng’rs</i> , 516 F.3d 1021 (D.C. Cir. 2008).....	20, 31, 32
<i>Pregis Corp. v. Kappos</i> , 700 F.3d 1348 (Fed. Cir. 2012) .....	36, 40, 41, 46
<i>Saab Cars USA, Inc. v. United States</i> , 434 F.3d 1359 (Fed. Cir. 2006) .....	6
<i>Sage Prods., Inc. v. Devon Indus., Inc.</i> , 126 F.3d 1420 (Fed. Cir. 1997) .....	20

<i>Symantec Corp. v. Computer Assocs. Int’l, Inc.</i> , 522 F.3d 1279 (Fed. Cir. 2008) .....	35
<i>Syntex (U.S.A.), Inc. v. USPTO</i> , 882 F.2d 1570 (Fed. Cir. 1989) .....	45
<i>United States v. Pierce Auto Freight Lines, Inc.</i> , 327 U.S. 515 (1946).....	34
<i>United States v. Salerno</i> , 481 U.S. 739 (1987).....	27
<i>Velasco v. Gov’t of Indonesia</i> , 370 F.3d 392 (4 <sup>th</sup> Cir. 2004) .....	8
<i>Williams Mfg. Co. v. United Shoe Mach. Corp.</i> , 121 F.2d 273 (6 <sup>th</sup> Cir. 1941) .....	5
<i>Wind River Mining Corp. v. United States</i> , 946 F.2d 710 (9th Cir. 1991) .....	19

## STATUTES

5 U.S.C. § 701 .....	3
5 U.S.C. § 701(a)(1).....	passim
28 U.S.C. § 1291 .....	1
28 U.S.C. § 1295(a)(1).....	15, 17
28 U.S.C. § 1331 .....	1
28 U.S.C. § 2401 .....	passim
28 U.S.C. § 2401(a) .....	passim
35 U.S.C. § 41(a)(7).....	6

35 U.S.C. § 255 .....	45
35 U.S.C. § 282 .....	38, 40
35 U.S.C. § 301 .....	passim
35 U.S.C. § 301-07.....	5
35 U.S.C. § 311-19.....	5
35 U.S.C. § 321-29.....	5
35 U.S.C. § 351 .....	5, 36
35 U.S.C. § 371(c) .....	5
35 U.S.C. § 371(d) .....	5, 7

## RULES

Federal Rule of Appellate Procedure 32(a)(7)(B) .....	49
---	----

## REGULATIONS

37 C.F.R. § 1.17(l) .....	6
37 C.F.R. § 1.17(m) .....	6
37 C.F.R. § 1.137(b) .....	6, 8, 33
37 C.F.R. § 1.135 .....	5
37 C.F.R. § 1.138 .....	5
37 C.F.R. § 1.322 .....	10, 32, 33
37 C.F.R. § 1.495 .....	5
37 C.F.R. § 1.495(b) .....	7

*Hire Order Ltd. v. Marianos*, Appellant's Br., 2011 WL 5040509.....24

## STATEMENT OF RELATED CASES

There are no other appeals arising from the District Court action below. The USPTO is only aware of the following case that may be directly affected by the outcome of this appeal: *Cadence Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC*, No. 11-cv-733 (D. Del.).

## STATEMENT OF JURISDICTION

Plaintiffs-Appellants Exela Pharma Sciences, LLC, Exela Pharmsci, Inc., and Exela Holdings, Inc. (collectively “Exela”), sought to vest the District Court with subject matter jurisdiction over their claims pursuant to 28 U.S.C. §§ 1331 and 1338(a). The District Court ultimately agreed with Defendants-Appellees’ position that it lacked subject matter jurisdiction over Exela’s claims, and it is this ruling that forms the basis of Exela’s instant appeal.

This Court possesses jurisdiction over this appeal, pursuant to 28 U.S.C. § 1291, from the final order dismissing Exela’s complaint. JA 1427-29.

## STATEMENT OF THE ISSUES

1. Whether the District Court correctly concluded that, under controlling regional circuit authority, Exela's APA claims were required to be filed within six years of final agency action, regardless of when Exela suffered injury.
2. Whether the District Court erred in concluding that, notwithstanding this Court's decision in *Aristocrat*, Congress intended third-parties to avoid putative infringement liability through APA review of alleged procedural irregularities before the USPTO.

## STATEMENT OF THE CASE

1. Exela filed its complaint against the USPTO on April 26, 2012, in the United States District Court for the Eastern District of Virginia. A0019. The complaint generally alleged that the USPTO incorrectly utilizes an "unintentional" standard in adjudicating *ex parte* requests by patent applicants for the revival of abandoned international patent applications, when – in Exela's view – the Patent Act requires an applicant to meet a higher "unavoidable" standard. A0026-41. Exela averred that it was injured by USPTO's use of this standard when the owner of a patent that issued after the USPTO revived an international patent application under the "unintentional" standard sued Exela – in the United States District Court for the

District of Delaware – for infringement. A0029-0030 ¶¶17-22; A0033-0034 ¶40.

Because this Court’s decision in *Aristocrat Techs. Australia Pty. Ltd. v. Int’l Game Tech.*, 543 F.3d 657, 663 (Fed. Cir. 2008), precluded Exela from raising its claim concerning improper revival in the Delaware infringement action, Exela sought the exact same review indirectly by suing the USPTO under the Administrative Procedure Act (“APA”), 5 U.S.C. § 701, *et seq.*, in the Eastern District of Virginia.

2. On June 25, 2012, the USPTO moved to dismiss Exela’s complaint. A0319-20. The USPTO specifically argued that Exela’s claims were time-barred under the applicable statute of limitations, *see* 28 U.S.C. § 2401, that Exela lacked constitutional and prudential standing to maintain its claims, and that – primarily as a result of this Court’s decision in *Aristocrat* – Congress had precluded judicial review over claims of improper revival by putative third-party infringers, *see* 5 U.S.C. § 701(a)(1), regardless of the forum in which such allegations are brought. A0322-0374. In an order and memorandum opinion dated August 22, 2012, the District Court (O’Grady, J.) denied the USPTO’s motion. A0008-0016.

3. After the USPTO filed its answer on September 4, 2012, SCR Pharmatop and Cadence Pharmaceuticals – the entities that sued Exela for infringement in the District of Delaware – sought to intervene in the action as defendants. A5001-03. The District Court granted that motion through an order dated October 2, 2012.

A5032-33.

4. On November 6, 2012, both the USPTO and the intervenors jointly moved the District Court to reconsider its earlier statute of limitations ruling based upon the Fourth Circuit’s intervening decision in *Hire Order, Ltd. v. Marianos*, 698 F.3d 168 (4<sup>th</sup> Cir. 2012).<sup>1</sup> After full briefing and oral argument, the District Court granted the motion, holding that the Fourth Circuit’s construction of § 2401 in *Hire Order* – on virtually identical circumstances to those presented here – mandated the conclusion that Exela’s claims were barred on limitations grounds. A0001-6.

This timely appeal ensued.

## STATEMENT OF THE FACTS

### 1. Revival of Abandoned Patent Applications

Even before it promulgated the 1952 version of the Patent Act, Congress had clearly provided that administrative proceedings related to patent examination (with particularized and limited exceptions) were to move forward on an *ex parte* basis – *i.e.*, between the USPTO and the patent applicant/owner only. *See, e.g.*,

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<sup>1</sup> After the District Court’s denial of the USPTO’s initial motion to dismiss, Exela moved for summary judgment on the merits of its claims. A0435-0437. Once the Fourth Circuit issued *Hire Order*, however, the District Court continued merits briefing in order to allow the USPTO and the intervenors to seek reconsideration. A5034.

*Williams Mfg. Co. v. United Shoe Mach. Corp.*, 121 F.2d 273, 277 (6<sup>th</sup> Cir. 1941).<sup>2</sup>

As explained below, administrative petitions seeking the revival of abandoned patent applications are one such type of *ex parte* proceeding.

In the international context, a foreign inventor seeking to apply for a patent in the United States can, *inter alia*, file an international patent application and prosecute the patent in the United States pursuant to the process outlined in the Patent Cooperation Treaty (“PCT”). *See* 35 U.S.C. § 351, *et seq.* Consistent with the PCT, USPTO regulation, *see* 37 C.F.R. § 1.495, provides that the international patent applicant must provide “[a] copy of the international application” and “[t]he basic national fee” within thirty months of the “priority date.” *Id.* Failure to meet these requirements results in abandonment of the application. *See* 35 U.S.C. § 371(d).<sup>3</sup>

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<sup>2</sup>Indeed, under the current Patent Act, a third-party is only entitled to intervene and participate before the USPTO during administrative reexamination, *see* 35 U.S.C. §§ 301-07, or more recently as a result of the America Invents Act, post-grant and *inter partes* review, *see id.* §§ 311-19; 321-29. This limited right of administrative participation is thus limited to a single context – the review of the merits of an issued patent, and not the administrative and procedural minutiae that are a part of virtually all patent examinations.

<sup>3</sup>A patent application may become abandoned for a variety of reasons. For example, a patent can be expressly abandoned, *see* 37 C.F.R. § 1.138, or it can become abandoned as a result of a failure to prosecute, *see id.* § 1.135. The failure to timely file the documents and fees required by 35 U.S.C. § 371(c) to enter the national stage constitutes an example of the latter form of abandonment. *See* 35 U.S.C. § 371(d).

Congress has provided for the revival of abandoned patents under two separate standards, each of which is invoked by the patent applicant through the filing of an *ex parte* petition with the USPTO. The first standard provides for the revival of patent applications under the straight-forward “unintentional” delay standard, but is one that entails a high cost. The second provides for the revival of patent applications under a less expensive, but more stringent, “unavoidable” delay standard. *See* 35 U.S.C. § 41(a)(7). Consistent with § 41(a)(7), the USPTO promulgated 37 C.F.R. § 1.137(b) in 1982, providing for the revival of unintentionally abandoned patent applications, and § 1.17(l) and § 1.17(m) establish separate fee provisions for petitions filed under the unintentional and unavoidable delay standards.<sup>4</sup> As the District Court recognized, the USPTO has

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<sup>4</sup>Exela dedicates an extraordinary portion of its opening brief to an explanation of the ultimate merits of its legal position that the USPTO can only revive an abandoned international application under the “unavoidable” standard. *Brief*, at 6-9; 22-25. This is particularly strange given that the District Court never passed on the merits of Exela’s claims. And as the Supreme Court has long held, the merits of a particular claim are irrelevant to the threshold question of whether the Article III courts possess jurisdiction to entertain that claim. *See, e.g., Ex Parte McCardle*, 74 U.S. (7 Wall.) 506, 514 (1868) (“Without jurisdiction the court cannot proceed at all in any cause. Jurisdiction is the power to declare the law, and when it ceases to exist, the only function remaining to the court is that of announcing the fact and dismissing the cause.”); *Saab Cars USA, Inc. v. United States*, 434 F.3d 1359, 1367 (Fed. Cir. 2006). It should suffice to say here that the USPTO does not concur with Exela’s position that “[t]here is no reasonable dispute that the PTO’s” revival standard “is not authorized by 35 U.S.C. § 371(d).” *Brief*, at 22. To the extent that this Court were to find that the District Court has

not deviated from the use of this “unintentional” standard in the revival context. Notably, nowhere within the provisions of the Patent Act or the USPTO’s regulations is the participation of third parties authorized in the revival process.

## **2. USPTO’s 2003 Revival of PCT/FR01/01749**

On June 6, 2000, SCR Pharmatop (“SCR”), a French company, filed French patent application FR 00 07231 for a “new method for obtaining aqueous formulations with active principles susceptible to oxidation and the aqueous solutions thus obtained.” A0032 ¶31. A year later, on June 6, 2001, SCR filed in the United States international patent application number PCT/FR01/01749 at the USPTO, claiming priority to FR 00 07231. *Id.* ¶32. The USPTO assigned the application serial number 10/332,060, which served as the national stage application for PCT/FR01/01749. *Id.*

SCR was thus required to fulfill the above paperwork and fee requirements by December 6, 2002 – *i.e.*, 30 months from the filing of FR 00 07231 – to avoid abandonment of the PCT/FR01/01749 application. A0032 ¶33. *See* 35 U.S.C. § 371(d); 37 C.F.R. § 1.495(b). SCR failed, however, to make the required submissions by that date, and the application became abandoned. *Id.* ¶¶33-34.

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jurisdiction to decide Exela’s claims, it should remand the case to the District Court to decide the merits in the first instance.

Less than one month later, on or around January 2, 2003, SCR filed an *ex parte* petition, pursuant to 37 C.F.R. § 1.137(b), with the USPTO seeking to revive PCT/FR01/01749 in the United States (*i.e.*, 10/332,060). In its submission, SCR asserted that the entire delay in meeting the national stage requirements was “unintentional.” *Id.* On April 25, 2003, USPTO granted SCR’s petition, finding that “all requirements under 37 C.F.R. § 1.137(b) ha[d] been met” and requiring the submission of a signed oath or declaration. A0352.<sup>5</sup> SCR filed the required declaration, and PCT/FR01/01749 was revived. At the conclusion of prosecution, on January 31, 2006, SCR’s application issued as U.S. Patent No. 6,992,218 (“the ‘218 patent”). A0034 ¶43.

### 3. Delaware Patent Infringement Litigation Against Exela

Cadence Pharmaceuticals, Inc. (“Cadence”) holds New Drug Approval (“NDA”) No. 022450 for OFIRMEV®, an intravenous formulation of acetaminophen (*i.e.*, Tylenol) available in the United States. A0360 ¶40. The

<sup>5</sup>Although the majority of this factual discussion is derived from Exela's complaint, it bears mentioning that because the USPTO sought dismissal under Federal Rule 12(b)(1), the District Court was entitled to review materials outside the four corners of that complaint. *See, e.g., Velasco v. Gov't of Indonesia*, 370 F.3d 392, 398 (4<sup>th</sup> Cir. 2004). And in any event, because any evidence extrinsic to Exela's complaint is found within the administrative record of proceedings before the USPTO, the District Court was entitled to review the same even in the Federal Rule 12(b)(6) context. *See Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083-84 (D.C. Cir. 2001).

Orange Book lists the '218 patent and U.S. Patent No. 6,028,222 (“the '222 patent”) for OFIRMEV®. A0035 ¶47. Exela submitted ANDA No. 20-3092 to the FDA seeking approval to engage in the commercial manufacture, use, sale, or offer for sale, and/or importation of Acetaminophen Injection, 10 mg/mL, 100 mL vials (“Exela Generic”), as a generic version of OFIRMEV®. A0363 ¶42.

On August 8, 2011, SCR and Cadence filed suit – in the United States District Court for the District of Delaware – against Exela and other defendants alleging infringement of both the '218 patent and the '222 patent. A0029 ¶¶17; A0035 ¶¶49. In that litigation, SCR and Cadence have alleged that their patents are valid and that Exela's submission of its ANDA application – as well as any commercial manufacture, import, use, offer for sale, or sale of the Exela Generic – constitutes an infringement of the patents-in-suit. A0354-0371. That lawsuit remains pending at this time, after the District of Delaware held a bench trial in May 2013.

#### **4. Exela's Attempts to Avoid Infringement Liability By Challenging the USPTO's 2003 Revival**

After ostensibly reviewing the USPTO file wrapper for the prosecution of the '218 patent in preparing its defense of the Delaware infringement action, *see Aristocrat*, 543 F.3d at 663, Exela began an affirmative attempt to avoid any potential infringement liability by challenging the USPTO's revival of the

underlying application over eight years earlier.

First, on November 11, 2011, over eight and a half years after the USPTO's revival decision, Exela filed a petition with the USPTO asking the agency to "reconsider and withdraw its petition decision reviving abandoned U.S. patent application [N]o. 10/332,060, which ultimately issued as U.S. Patent No. 6,992,218." A0056-0067; *see also* A0035 ¶50. Nor was Exela at all bashful about the impetus for its request, providing that without the USPTO's revival, it would not be facing putative infringement liability on the '218 patent. A0059 ("But for the PTO's improper revival and issuance of the '218 patent, this patent would not be a part of the pending litigation brought against Exela . . ."). On February 17, 2012, USPTO issued a Letter explaining as follows:

As a third party to an *ex parte* proceeding, petitioner is not in a position to demand that the USPTO act to vacate a prior decision unless specifically authorized by statute or regulation. In particular, neither the patent statute nor its implementing regulations, confer a right upon a third party to intervene or otherwise challenge the Office's decision to revive the international application. Information submitted to the Office regarding a patent that is not in reexamination must be consistent with 35 USC § 301, 37 CFR §§ 1.322 or 1.501, or the standards discussed in MPEP § 2207. The action requested by the third party here is not specifically authorized by statute or regulation, and the communication is not a proper submission under 35 USC § 301, 37 CFR §§ 1.322 or 1.501, or the standards discussed in MPEP § 2207. As petitioner lacks standing, the Office will not act as requested.

A0068-69. Accordingly, USPTO "decline[d] to take any action on petitioner's

request” and returned Exela’s petition fee. *Id.* USPTO also explained that it would not make the petition a part of the record in the file wrapper for the ’218 patent; *i.e.*, the petition – for purposes of the USPTO – was never even filed.

Expressly recognizing this Court’s holding in *Aristocrat* that Congress did not wish for putative third-party infringers to utilize this *exact argument* in defense of infringement liability, A0030 ¶24, Exela filed this action – in the Eastern District of Virginia – against the USPTO on April 26, 2012. A0026-41. Although Exela’s complaint maintained that the USPTO erred in granting SCR’s 2003 *ex parte* revival petition, it took issue – in each of the counts of its complaint – only with the generic legal standard (*i.e.*, “unintentional”) that the USPTO utilizes in adjudicating requests for the revival of international patent applications. A0036-40. Indeed, Exela specifically eschewed any reliance on “[t]he propriety of [SCR’s] claim [of] un-intentionality” in its abandonment of the underlying application and conceded that “the circumstances under which the abandonment [of the PCT/FR01/01749 application] occurred are not currently before this Court.” A0033 n.2.

## **5. The District Court’s Decisions**

a. In an order and memorandum opinion issued on August 22, 2012, the District Court denied the USPTO’s initial motion to dismiss.

On the issue of timeliness, the District Court expressly tied the accrual of an APA cause of action to the moment that Exela “suffered an injury in fact,” no matter how temporally-divorced from the actual USPTO decision itself. A0009.

More specifically, the District Court held:

Defendants argue that Plaintiffs’ untimely filed their lawsuit nine years after the PTO’s 2003 revival decision. However, Plaintiffs could not have filed a lawsuit in federal court until they had suffered an injury in fact. Plaintiffs’ alleged injury occurred in 2011, when the PTO’s allegedly improper revival decision enabled the ’218 licensee to file an infringement action against Plaintiffs.

*Id.*

On whether Congress has precluded putative third-party infringers from seeking judicial review of the USPTO’s decisions on revival petitions brought *ex parte* by other entities, the District Court acknowledged this Court’s decision in *Aristocrat* with respect to the unavailability of “improper revival” as a basis to avoid infringement liability. A0013. But the District Court then proceeded to limit this Court’s holding to a “determination that a revival decision could not be asserted *defensively* in an infringement action.” *Id.* (emphasis added). To the District Court, the fact that Exela had presented the exact same issue, and for the exact same purpose (*i.e.*, to avoid infringement liability), “in a separate cause of action against the PTO, rather than as a defense in the underlying infringement suit” was sufficient to “permit them to escape the Ninth Circuit’s [sic] holding in

*Aristocrat.*” A0014.

b. The District Court reversed its timeliness ruling, however, in the order and memorandum opinion it issued on the USPTO, SCR, and Cadence’s joint motion for reconsideration.

In this regard, the District Court recognized that its earlier decision on timeliness – which tied accrual of an APA claim for statute of limitations purposes to the time when a litigant suffers an injury in fact and is entitled to file a civil action – was inconsistent with controlling Fourth Circuit precedent after *Hire Order, Ltd. v. Marianos*, 698 F.3d 168 (4<sup>th</sup> Cir. 2012).<sup>6</sup> More specifically, the District Court acknowledged that *Hire Order* held “that the statute of limitations began to run as soon as the final agency action occurred regardless of when the injury to a particular party occurred.” A0003-0004. The District Court continued to analyze each of Exela’s individual APA claims, and held that those claims were “strikingly similar” to those rejected in *Hire Order*.<sup>7</sup> The District Court ultimately

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<sup>6</sup>Contrary to Exela’s comment, *Brief*, at 40 n.6, the District Court was free to reconsider any of its interlocutory decisions (even *sua sponte* if desired), *see Am. Canoe Ass’n v. Murphy Farms, Inc.*, 326 F.3d 505, 514-15 (4<sup>th</sup> Cir. 2003), and thus whether *Hire Order* in actuality changed the Fourth Circuit’s jurisprudential landscape is singularly without significance.

<sup>7</sup>In particular, the District Court held that Exela’s “challenge to an agency’s decision regarding which standard to apply across the board, rather than a determination regarding *how* to apply a standard,” was the very type of “facial challenge” that was the focus of *Hire Order*. A0004.

concluded that because any final agency action here occurred more than six years before the filing of Exela's Eastern District of Virginia action, Exela's claims were barred under § 2401's statute of limitations. A0003-0006. Finally, the District Court held that Exela's 2011 reconsideration request could not reset the limitations clock because, "the agency did not deny, but rather refused to consider, [Exela's] request." A0002-0003 (citing *ICC v. Brotherhood of Locomotive Engineers*, 482 U.S. 270 (1987)).

### **SUMMARY OF THE ARGUMENT**

In this appeal, in order to defend against – or ameliorate the putative injury resulting from – another civil action alleging its infringement of an issued patent, Exela challenges a rule on which the USPTO relied in deciding, in 2003, an *ex parte* petition filed by another entity. Two issues are presented to this Court: (1) whether Exela's 2012 judicial complaint, which sought judicial review of the USPTO's 2003 revival decision, was filed within the applicable statute of limitations; and (2) whether Congress intended for putative third-party infringers, such as Exela, to obtain judicial review of such revival decisions under the APA.

The District Court correctly held Exela's APA challenge to be barred by the applicable six-year statute of limitations mandated by 28 U.S.C. § 2401(a). This Court's jurisprudence clearly provides that when appellate jurisdiction is premised

upon 28 U.S.C. § 1295(a)(1), it is the law of the regional circuit (here, the Fourth Circuit) that applies to statute of limitations questions that are not unique to patent law. In *Hire Order, Ltd. v. Marianos*, 698 F.3d 168 (4<sup>th</sup> Cir. 2012), the Fourth Circuit held that an APA claim accrues at the time of the final agency action at issue, regardless of when the particular plaintiff is injured by that decision. The *Hire Order* challenge – which sought to invalidate an agency decision as being inconsistent with the governing statutory provisions – is virtually identical to Exela’s challenge on all levels, and as such, required the dismissal of Exela’s complaint. And Exela’s 2011 reconsideration request, which USPTO dispatched under its rules prohibiting *ex parte* participation without in any way reconsidering its earlier revival decision, cannot serve to restart the limitations clock.

The District Court did, however, err in concluding that Congress did not intend to preclude third-parties from defending against potential infringement liability by seeking APA review of USPTO revival decisions. This conclusion is completely inconsistent with this Court’s holding in *Aristocrat* that Congress – in delineating those remedies available under the Patent Act to those accused of infringement – expressly refused to include “improper revival” as an option. Permitting APA review on the very same question at the behest of the very same party within the very same context would render *Aristocrat* a pragmatic dead letter.

In the end, Congress’s intent to preclude APA review of USPTO revival decision at the behest of putative third-party infringers is not just “fairly discernible” from the Patent Act, it is obvious.

## **ARGUMENT**

### **I. STANDARD OF REVIEW**

This Court reviews the District Court’s grant of a motion to dismiss – whether pursuant to Federal Rule 12(b)(1) or 12(b)(6) – *de novo*. *See, e.g., Hewlett-Packard Co. v. Acceleron LLC*, 587 F.3d 1358, 1361 (Fed. Cir. 2009); *McCauley v. Home Loan Inv. Bank, F.S.B.*, 710 F.3d 551, 554 (4<sup>th</sup> Cir. 2013).

### **II. EXELA’S CLAIMS ARE TIME-BARRED UNDER CONTROLLING REGIONAL CIRCUIT AUTHORITY**

In dismissing on statute of limitations grounds, the District Court held that, under controlling regional circuit authority, Exela was required to file its APA claims within six years of the “final agency action” that it sought to challenge – *i.e.*, the USPTO’s 2003 revival decision.

The vast majority of the arguments that Exela asserts in its opening brief have been unequivocally rejected in authority that is binding on this Court. First, despite explicit authority to the contrary, Exela suggests that this Court’s own jurisprudence (and not that of the pertinent regional circuit) should govern the instant statute of limitations question. Second, Exela reasserts that its APA claims

did not accrue until it suffered an injury in fact (*i.e.*, being sued for infringement of the '218 patent), and that it can avoid the APA's statute of limitations because it has presented a "substantive" challenge to the USPTO's revival standard – notwithstanding the fact that the Fourth Circuit has rejected both arguments in no uncertain terms, and under virtually identical circumstances. And finally, Exela maintains that its unsanctioned attempt to obtain administrative reconsideration at the USPTO – one the agency did not even consider substantively – is sufficient to reset the limitations clock.

None of these arguments has any merit, and this Court should affirm the District Court's dismissal of Exela's claims.

**A. As Exela Conceded Below, the Fourth Circuit's Statute of Limitations Jurisprudence Governs this Court's Analysis**

Time and again, this Court has held that, when its jurisdiction over an appeal is premised on 28 U.S.C. § 1295(a)(1),<sup>8</sup> it "defers to the law of the regional circuits on matters of procedural law that do not implicate issues of patent law, *such as statute of limitations rulings.*" *Landmark Screens, LLC v. Morgan, Lewis &*

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<sup>8</sup>Section 1295(a)(1) vests this Court with jurisdiction over appeals "from a final decision of a district court of the United States . . . in any civil action arising under . . . any Act of Congress relating to patents or plant variety protection." 28 U.S.C. § 1295(a)(1).

*Bockius, LLP*, 676 F.3d 1354, 1361-62 (Fed. Cir. 2012) (emphasis added).<sup>9</sup> And it is presumably for this reason that Exela – during proceedings in the District Court – openly conceded that Fourth Circuit authority on the application of the pertinent statute of limitations would apply to its APA claims. A0123 (“The timeliness of Exela’s complaint under 28 U.S.C. § 2401(a) is controlled by prior Supreme Court and Fourth Circuit case law.”).

Notwithstanding its concession before the District Court, and this Court’s conclusive decision in *Landmark Screens*, Exela actually “submits that Federal Circuit law should govern” “the application of § 2401(a).” *Brief*, at 33 n.5. Exela’s position is spurious, and is premised solely upon a quotation in a prior decision of this Court – *Bray v. United States*, 785 F.2d 989 (Fed. Cir. 1986) – that Exela takes wildly out of context. As opposed to the question of which circuit court’s authority on a given topic will *govern* this Court’s adjudication of a given argument, this Court in *Bray* considered only the broader question of which court – this Court or a regional circuit – possessed appellate *jurisdiction* to *adjudicate* a statute of limitations inquiry. *See Bray*, 785 F.2d at 991-93.

As such, there can be little doubt that the Fourth Circuit’s decisional

<sup>9</sup>As in *Landmark Screens*, which concerned the application of a statute of limitations found within California common law, *see Landmark Screens*, 676 F.3d at 1361-62, the statute of limitations at issue in this appeal – 28 U.S.C. § 2401(a) –

authority on the application of the statute of limitations governs this Court's review of the District Court's dismissal.

**B. The Fourth Circuit's *Hire Order* Decision Mandated Dismissal of Exela's APA Claims**

As the District Court explained in its reconsideration decision, the Fourth Circuit's recent decision in *Hire Order, Ltd. v. Marianos*, 698 F.3d 168 (4<sup>th</sup> Cir. 2012), on APA claims that were "strikingly similar" to those brought by Exela here, mandated the dismissal of Exela's complaint. For this reason, before proceeding to an analysis of Exela's limitations arguments in this Court, the USPTO will first provide a brief discussion of both § 2401(a) and the Fourth Circuit's decision in *Hire Order*.

1. Pursuant to 28 U.S.C. § 2401(a), "every civil action commenced against the United States shall be barred unless the complaint is filed within six years after the right of action first accrues." This six-year statute of limitations applies to APA actions. *See Jersey Heights Neighborhood Ass'n v. Glendenning*, 174 F.3d 180, 186 (4<sup>th</sup> Cir. 1999). An APA action accrues on the date of the "final agency action." *See id.*; *see also Harris v. FAA*, 353 F.3d 1006, 1010 (D.C. Cir. 2004). Strong policy considerations undergird the strictness of this statute of limitations. *See Wind River Mining Corp. v. United States*, 946 F.2d 710, 715 (9th Cir. 1991) ("The

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is codified *outside* the Patent Act.

government's interest in finality outweighs a late-comer's desire to protest the agency's action . . . .")

Unlike an ordinary statute of limitations,<sup>10</sup> the time limit in "section 2401(a) creates a jurisdictional condition attached to the government's waiver of sovereign immunity." *Hardin v. Jackson*, 625 F.3d 739, 740 n.1 (D.C. Cir. 2010) (internal quotation marks omitted). This condition is unwaivable, proscribes federal jurisdiction, and is not subject to normal exceptions, such as equitable tolling or the continuing violation theory. *See P & V Enters. v. U.S. Army Corps of Eng'rs*, 516 F.3d 1021, 1026-27 (D.C. Cir. 2008); *Ctr. for Biol. Diversity v. Hamilton*, 453 F.3d 1331, 1335-36 (11<sup>th</sup> Cir. 2006).

2. *Hire Order* presents a nearly identical set of circumstances to those presently before this Court. The plaintiffs in *Hire Order* were firearms dealers who, after obtaining their federal firearms licenses in 2008, brought an APA claim in district

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<sup>10</sup> Exela's brief sets up a straw man when it attempts to create a dichotomy between statutes of limitations and of repose, arguing that the nomenclature is of some difference for purposes of the District Court's dismissal. *Brief*, at 29-33. The short answer to this line of reasoning is that because Exela did not raise it before the District Court, it is considered waived on appeal. *See, e.g., Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1426 (Fed. Cir. 1997) ("[T]his court does not 'review' that which was not presented to the district court."). In any event, the only point of Exela's discussion is that for purposes of a statute of limitations, such as § 2401, the limitations period is connected to the point at which "the right of action accrues," *Brief*, at 31, which the Fourth Circuit in *Hire Order* pinpointed as the date of "final agency action," not the date of injury. *See*

court challenging a 1969 Revenue Ruling that “prohibited federal firearms licensees from ‘sell[ing] firearms or ammunition at a gun show held on premises other than those covered by his license.’” *Hire Order*, 698 F.3d at 169 (quoting *Rev. Rul.* 69-59). Plaintiffs maintained – like Exela here – that the Revenue Ruling, to the extent that it sought to regulate *out-of-state* gun sales, was inconsistent with the pertinent statutory framework (*i.e.*, the Gun Control Act). *See id.* And as such, their challenge was not to the Revenue Ruling in total, or even to the Revenue Ruling’s prohibition on out-of-state gun sales generally; to the contrary, the *Hire Order* plaintiffs challenged the Revenue Ruling only to the extent that it precluded a firearms dealer “from one state [from] sell[ing] firearms at a gun show in another state to a dealer from the state in which the gun show is located.” *Id.* Put simply, the *Hire Order* plaintiffs sought to challenge the Revenue Ruling only to the extent that it precluded a particular type of out-of-state gun sale.

The Fourth Circuit affirmed the district court’s dismissal on statute of limitations grounds. *See id.* at 170. Reiterating that “[a] cause of action governed by § 2401(a) accrues or begins to run at the time of ‘final agency action,’” the Fourth Circuit held that the *Hire Order* plaintiffs’ APA claim accrued in 1969 with

*infra* Part I.B.2.

the publication of the challenged Revenue Ruling. *Id.* (quoting *Jersey Heights*, 174 F.3d at 186). This was so even though the *Hire Order* plaintiffs did not become firearms dealers until 2008, *see id.*, and so literally could not have challenged the ruling within six years of its publication in 1969. Of premier importance for this appeal, the Fourth Circuit rejected the lynchpin of Exela’s argument here – *i.e.*, that any APA claim cannot accrue until one suffers an injury sufficient to provide a cause of action to file – and differentiated the very cases on which Exela premises its argument:

The contention of Hire Order and Privott that their cause of action did not accrue until they became federally licensed firearms dealers in 2008 *utterly fails*. The cases on which they rely offer no support for their position.

*Id.* (emphasis added) (citing, e.g., *Bay Area Laundry & Dry Cleaning Pension Trust Fund v. Ferbar Corp. of California, Inc.*, 522 U.S. 192, 201 (1997); *Crown Coat Front Co. v. United States*, 386 U.S. 503, 511 (1967)). This was so because – the Fourth Circuit held – the type of APA challenge that the *Hire Order* plaintiffs raised was “facial” for purposes of statute of limitations analysis. *See id.*

As the District Court here cogently recognized, Fourth Circuit authority now clearly provides that “the statute of limitations beg[ins] to run as soon as the final agency action occurred regardless of when the injury to a particular party occurred.” A0003-0004.

3. Ostensibly undeterred by the Fourth Circuit’s binding decision, Exela’s opening brief presents a number of arguments that were completely and unequivocally rejected in *Hire Order*.<sup>11</sup>

a. First, in a lengthy section of its brief in which it does not once even cite to *Hire Order*, Exela continues to maintain that its “challenge to the [US]PTO’s Revival Decision did not accrue until it was injured in 2011.” *Brief*, at 33-39.

Quoting directly from *Bay Area Laundry*, Exela argues that its claim did not accrue until it could “file suit and obtain relief,” and that pinpointing accrual at the time that a litigant suffers injury “is consistent with the commonsense rule requiring injury before a right of action can accrue.” *Id.* at 33 (quoting *Bay Area Laundry*, 522 U.S. at 201); 36. According to Exela, its “challenge to the specific revival decision accrued no earlier than August 2011,” because “[i]t was then that [SCR] . . . sued Exela for alleged infringement of the ’218 patent,” and before “that time, Exela had no legal interest in the validity or enforceability of the ’218 patent.” *Id.* at 34.

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<sup>11</sup>Exela also half-heartedly maintains that the USPTO’s revival decision was not technically “final agency action”; rather, Exela suggests that the USPTO’s ultimate *issuance* of the ’218 patent was the “final agency action” from which its injury is derived, and thus, when its APA claim accrued. *Brief*, at 43. Exela never raised this position in this District Court, and for good reason – it provides them with no assistance in surviving application of the statute of limitations. The USPTO issued the ’218 patent on January 31, 2006, and Exela’s District Court

Whatever merit these arguments might have in the abstract – and the USPTO maintains that they are meritless – is a mere academic exercise, because each of these arguments was made in *Hire Order* and clearly rejected by the Fourth Circuit in a published (and thus binding) opinion. Like Exela here, the *Hire Order* plaintiffs argued that under controlling Supreme Court precedent – including *Bay Area Laundry* and *Crown Coat* – their action was timely under § 2401(a) because a cause of action first “accrues” when the plaintiff is injured. *Hire Order Ltd. v. Marianos*, Appellant’s Br., 2011 WL 5040509, at \*3-\*4 (“Afton’s and Privott’s right of action first accrued in 2008 when they obtained their federal firearms licenses because the ‘right of action of which § 2401(a) speaks’ is ‘the right to file a civil action in the courts against the United States.’”). They further argued, again like Exela here, that to hold otherwise would lead to absurd results – *i.e.*, that the appellants would be prevented from challenging the revenue ruling even though they were not in existence within six years of the ruling’s promulgation. *Id.* at \*10 (“To deny Afton and Privott the opportunity to challenge Revenue Ruling 69-59 is [sic] approve the absurd result that only a person who was licensed within six years after Revenue Ruling 69-59 was issued could challenge it.”). But as stated above, the Fourth Circuit expressly held that these very arguments

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complaint was not filed until April 26, 2012, more than six years later.

“utterly fail[ed],” and that the cited Supreme Court decisions offered no support for their position in the instant APA context. *Hire Order*, 698 F.3d at 170 (emphasis added).

b. Exela also incorrectly maintains that because, “as opposed to a procedural challenge,” its APA claim was “an attempt to remedy a substantive error in a [US]PTO decision that exceeded” the agency’s “statutory authority,” it was free to file its complaint untethered to any statute of limitations. *Brief*, at 25-28.

While other Circuits may distinguish between so-called “procedural” and “substantive” challenges for statute of limitations purposes, *see, e.g., NLRB Union v. FLRA*, 834 F.2d 191, 196 (D.C. Cir. 1987), the Fourth Circuit drew no such distinction in *Hire Order*. The *Hire Order* plaintiffs claimed that the Internal Revenue Service (“IRS”) had erred in construing the Gun Control Act, and the prohibitions contained in the Revenue Ruling at issue were inconsistent with the express language of the statute. Exela’s APA claim here, which challenges the USPTO’s use of the “unintentional” standard in the adjudication of petitions to revive international patent applications, is similarly premised on the position that the USPTO erred in construing the provisions of the Patent Act. Because there is no material difference between the claims in these two cases, and the claims in

*Hire Order* were held to be time-barred, Exela's argument is unavailing.<sup>12</sup>

c. Finally, actually addressing the Fourth Circuit's decision for the first time, Exela maintains that unlike the so-called "facial" challenge raised in *Hire Order*, its APA claim regarding the USPTO's use of the "unintentional" standard is an "as applied" challenge; as such, its claim allegedly accrued at the time of its putative injury. For several reasons, this argument is without merit.

First, the District Court correctly concluded that Exela's APA claim here constituted a "facial" challenge to the regulation, just like the claim in *Hire Order*. Through a detailed review of the complaint, the District Court held that because Exela's claims challenged the USPTO's "decision regarding which standard to apply across the board, rather than a determination regarding *how* to apply a standard, [it was] a facial challenge rather than an as-applied challenge." A0004 (emphasis in original). As the District Court reasoned, Exela's APA challenge here it does not depend on any particular facts regarding the '218 patent, the reasons that the underlying patent application initially went abandoned, or the facts surrounding Exela's alleged infringement. In short, just as in *Hire Order*, Exela's

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<sup>12</sup>It bears noting that even if the distinction between "substantive" and "procedural" claims were a meaningful one in the Fourth Circuit for statute of limitations purposes, which it is not, this Court has characterized the very same statutory argument that Exela asserts here nothing more than a "procedural irregularity." *Aristocrat*, 543 F.3d at 663.

complaint *expressly* challenged only the legality of the rule itself, not whether the USPTO properly applied the rule to the specific facts surrounding why SCR abandoned PCT/FR01/01749 (*i.e.*, whether SCR’s abandonment was, in actuality, “unintentional”). A0033 n.2 (“The propriety of claiming un-intentionality and the circumstances under which the abandonment occurred are not currently before this Court.”).

The District Court’s analysis was completely consistent with, and indeed mandated by, *Hire Order*. A0006. Exela averred that the USPTO erred in construing the Patent Act to authorize revival of an international patent application under an “unintentional” standard; in *Hire Order*, plaintiffs averred that the IRS erred in construing the Gun Control Act to prohibit a certain type of out-of-state gun show transaction. Both APA claims were completely legal in nature, and both challenged the legality of a general standard, as opposed to the application of that standard to an evidentiary record.

Nor can there be any doubt that Exela’s attempt to equate the meaning of “facial challenge” for limitations purposes with the notion often utilized in constitutional jurisprudence – “that no set of circumstances exists under which the Act would be valid,” *United States v. Salerno*, 481 U.S. 739, 745 (1987) – is inconsistent with *Hire Order*. Exela remarkably argues as follows:

In a facial challenge, *such as in Hire Order*, the complainant attacks the regulation not under any particular set of facts, but, instead, as to every conceivable application of the rule.

*Brief*, at 40 (emphasis added). From this premise, Exela maintains that because its APA claim only challenges the USPTO’s application of the “unintentional” standard to international patent applications, it has presented an “as applied” challenge not subject to *Hire Order*.

But *Hire Order* was *not* an “attack” on the Revenue Ruling “as to [its] every conceivable application.” Although the Revenue Ruling at issue in *Hire Order* prohibited the sale of firearms “at a gun show held on premises other than those covered by [the] license,” the *Hire Order* plaintiffs only challenged the application of that to *one particular sale* (*i.e.*, a sale “from a dealer from one state . . . at a gun show in another state to a dealer from the state in which the gun show is located”). *Hire Order*, 698 F.3d at 169. There is simply no material difference – or any difference at all – between the nature of the APA challenge in *Hire Order*, and that which Exela sought to present to the District Court here.

Second, even classifying Exela’s APA claim as an “as-applied” challenge would not render that claim timely under § 2401. As the Fourth Circuit has held, § 2401(a) applies – and the six-year limitations period begins to run – upon the issuance of a “final agency action.” *See Jersey Heights*, 174 F.3d at 187; *see also*

*Dunn-McCampbell Royalty Interest, Inc. v. NPS*, 112 F.3d 1283, 1287 (5<sup>th</sup> Cir. 1987) (“An ‘as applied’ challenge must rest on final agency action under the APA. But absent some ‘final’ action, the APA will not provide a cause of action to challenge agency decisions.” (citations omitted)). Even if Exela’s APA claim was correctly categorized as an “as applied” challenge to the “unintentional” standard, the final agency action in which the *USPTO* “applied” that standard was the 2003 Revival Decision, which issued more than six years before Exela filed its complaint.

Nowhere within its brief, *Brief*, at 39-44, does Exela cite to any authority in support of its desired conclusion – that an “as applied” challenge allows a litigant to move the accrual of its APA claim from final agency action to the date of injury. Exela cannot identify any final agency action – within six years of April 26, 2012 – in which the *USPTO* applied the rule it sought to challenge in the District Court (*i.e.*, the “unintentional” standard) to *Exela* itself, or any of its intellectual property. *See Dunn-McCampbell*, 112 F.3d at 1287 (“The NPS has taken no action against Dunn-McCampbell that demands immediate compliance. It is a tautology that Dunn-McCampbell may not challenge the 9B regulations as applied until the Park Service *applies the regulations to Dunn-McCampbell*.” (emphasis added)) *Cf. Functional Music, Inc. v. FCC*, 274 F.2d 543, 546 (D.C. Cir. 1958) (holding that

one could seek subsequent APA “examination of a rule . . . for review of further *Commission action applying it*” (emphasis added)).

As such, Exela’s distinction between facial and as-applied challenges provides it no help in avoiding the District Court’s accurate application of § 2401 to its APA claims.

**C. Exela’s Perfunctory and Unsanctioned 2011 Request for Reconsideration Did Not Restart the § 2401 “Clock”**

Finally, Exela argues that its 2011 request for reconsideration (and the USPTO’s letter response to the same) serves as a *new* final agency action that reset the statute of limitations clock so as to allow it to seek APA review of the 2003 Revival Decision. Exela’s position – which would ultimately render the limitations period Congress mandated through § 2401(a) meaningless – is completely without merit, and the District Court correctly rejected it based on settled Supreme Court authority. A0002-0003 n.1.

First, there is a significant question as to whether Exela even pled an APA claim based on its 2011 reconsideration request, or the USPTO’s letter response. Although Exela’s complaint initially mentions the USPTO’s letter response, Exela never seeks any actual relief concerning that letter response (or its 2011 reconsideration request). A0040-0041. Indeed, throughout the numerous counts of its complaint, the only actual relief sought by Exela concerns the 2003 Revival

Decision itself, as well as USPTO’s “rules and regulations allowing for revival of abandoned international patent applications under the ‘unintentional’ standard.” A0036-0040. In short, other than the barest of conclusory statements, Exela’s complaint contains no allegation that suggests the impropriety of the USPTO’s “response” to Exela’s 2011 reconsideration request, and as such, Exela fails to plead a plausible claim that the USPTO erred in refusing to consider a third party collateral attack on an international patent application revival decision the agency issued eight years earlier. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (“[T]he tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to . . . [t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements.”).

But more substantively, the USPTO’s “response” to Exela’s reconsideration request cannot possibly be sufficient to allow Exela the restart the limitations clock, under the so-called “reopening” (or “reopener”) doctrine, on the USPTO’s 2003 revival decision. As Exela openly conceded, this doctrine is rather limited – it applies only to authorize “an otherwise stale challenge to proceed because ‘the agency opened the issue up anew,’ and then ‘reexamined and reaffirmed its [prior] decision.’” *Brief*, at 45 (quoting *P&V Enters. v. U.S. Army Corps of Eng’rs*, 516 F.3d 1021, 1023 (D.C. Cir. 2008)). Moreover, in order to avail itself of the

doctrine, a litigant must “demonstrate[] that the agency ha[s] undertaken a *serious, substantive* reconsideration of the rule.” *P&V Enters.*, 516 F.3d at 1024 (quoting *Nat’l Mining Ass’n v. U.S. Dep’t of Interior*, 70 F.3d 1345, 1352 (D.C. Cir. 1995) (emphasis added)). But as the Supreme Court has held, “where a party petitions an agency for reconsideration on the ground of ‘material error,’ *i.e.*, on the same record that was before the agency when it rendered its original decision, an order which *merely denies rehearing* of the prior order is not itself reviewable.” *ICC v. Brotherhood of Locomotive Engr’s*, 482 U.S. 270, 280 (1987) (emphasis added).

The USPTO’s “response” to Exela’s 2011 reconsideration request was actually the direct antithesis of the type of “serious, substantive reconsideration” of its 2003 revival decision necessary to invoke the “reopening doctrine.” In fact, as the record clearly demonstrates, the USPTO *refused* to reconsider or reexamine its prior decision – or the rule underlying that decision – in any way. Nor was the USPTO’s refusal premised at all on the merits of its prior decision; to the contrary, USPTO explained that Exela, as a third party to the *ex parte* revival proceeding, was not authorized by regulation or statute to challenge the revival decision:

As a third party to an *ex parte* proceeding, petitioner is not in a position to demand that the USPTO act to vacate a prior decision unless specifically authorized by statute or regulation. In particular, neither the patent statute nor its implementing regulations, confer a right upon a third party to intervene or otherwise challenge the Office’s decision to revive the international application. Information submitted to the Office regarding a

patent that is not in reexamination must be consistent with 35 USC § 301, 37 CFR §§ 1.322 or 1.501, or the standards discussed in MPEP § 2207. The action requested by the third party here is not specifically authorized by statute or regulation, and the communication is not a proper submission under 35 USC § 301, 37 CFR §§ 1.322 or 1.501, or the standards discussed in MPEP § 2207.

A0373. As a result, USPTO returned the petition fee and declined even to make the petition part of the record – hardly the close reexamination that is the *sine qua non* of the “reopening doctrine.”

The USPTO’s response neither affirmed nor rejected its 2003 Revival Decision; indeed, it fails even to mention the application of § 1.137(b) in the context of international patent applications. Instead, USPTO interpreted its own *procedural* rules and regulations—including 37 C.F.R. §§ 1.322 and 1.501 and M.P.E.P. § 2207—as well as 35 U.S.C. § 301 of the Patent Act, in finding that it was *not authorized* to reconsider the 2003 Revival Decision. Exela can therefore derive no benefit from the “reopening doctrine.”

In the end, as the Supreme Court itself has recognized, acceptance of Exela’s position here would render § 2401(a) and the Fourth Circuit’s construction of the statute in *Hire Order* meaningless. If a litigant could obtain judicial review of a long-settled agency decision simply by filing a perfunctory request for reconsideration with the agency regardless of whether the agency’s statutes, regulations, and rules permitted such a request, timeliness principles—which

ensure finality of agency decisions—would be rendered obsolete. *See Locomotive Engr's*, 482 U.S. at 281 (holding that there must be “a prohibition against the agency’s permitting, or a litigant’s achieving, perpetual availability of review by the mere device of filing a suggestion that the agency has made a mistake and should consider the matter again”); *see also Magnola Metallurgy, Inc. v. United States*, 508 F.3d 1349, 1357 (Fed. Cir. 2007).<sup>13</sup>

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As the Fourth Circuit held in *Hire Order*, an APA claim accrues at the time of the final agency action that is the subject of the underlying request for judicial review. Here, Exela’s claims accrued, at latest, in 2003, when the USPTO revived SCR’s international patent application. Accordingly, the District Court correctly held that Exela’s judicial complaint, filed well beyond April 2009, was barred by operation of the statute of limitations.

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<sup>13</sup>Even if Exela had adequately pled a plausible APA claim regarding the USPTO’s refusal to consider its 2011 reconsideration request, only the propriety of the agency’s refusal would be at issue (*i.e.*, whether the USPTO correctly concluded that, under its own rules, Exela – as a third-party – had no ability to seek reconsideration of an *ex parte* decision rendered during prosecution of another patent). And as the Supreme Court has held, such a decision can only be reversed on “a showing of the clearest abuse of discretion.” *Locomotive Engr's*, 482 U.S. at 278 (quoting *United States v. Pierce Auto Freight Lines, Inc.*, 327 U.S. 515, 534-35 (1946)).

### III. CONGRESS PRECLUDED THIRD-PARTIES FROM ATTEMPTING TO AVOID INFRINGEMENT LIABILITY THROUGH JUDICIAL REVIEW OF USPTO REVIVAL DECISIONS

The District Court also erroneously concluded that, despite Congress's conscious choice not to include the very issue that Exela raises here (*i.e.*, improper revival) as a means by which a putative third-party infringer can avoid liability for patent infringement, Congress simultaneously did not intend to preclude a separate APA cause of action by the same putative third-party infringer on the same issue. Perhaps recognizing the infirmity of the District Court's ruling on this score, Exela affirmatively discusses this issue in its opening brief.<sup>14</sup> *Brief*, at 50-55. Should this Court conclude that the District Court erred in holding Exela's claims time-barred, it should reverse the District Court's preclusion holding, which cannot be squared with the jurisprudence of this Court.

Although "[t]he APA confers a general cause of action upon persons 'adversely affected or aggrieved by agency action within the meaning of a relevant statute,' [it] withdraws that cause of action to the extent the relevant statute 'preclude[s] judicial review.'" *Block v. Comm. Nut. Inst.*, 467 U.S. 340, 345 (1984) (quoting 5 U.S.C. §§ 701(a)(1); 702). The Supreme Court framed this

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<sup>14</sup>As Exela implicitly concedes, the USPTO was not required to file a cross-appeal on this issue because a reversal would not "expand the judgment." *Symantec Corp. v. Computer Assocs. Int'l, Inc.*, 522 F.3d 1279, 1294 n.8 (Fed. Cir. 2008).

Court's inquiry as follows:

Whether and to what extent a particular statute precludes judicial review is determined not only from its express language, but also from the structure of the statutory scheme, its objectives, its legislative history, and the nature of the administrative action involved. Therefore, we must examine this statutory scheme “to determine whether Congress nevertheless foreclosed review *to the class to which the [plaintiff] belong[gs].*”

*Id.* at 345-46 (citations omitted) (quoting *Barlow v. Collins*, 397 U.S. 159, 173

(1970) (Brennan, J., concurring) (emphasis added)); *see also Pregis Corp. v.*

*Kappos*, 700 F.3d 1348, 1358 (Fed. Cir. 2012). Accordingly, the issue here is only

whether Congress intended to foreclose judicial review of USPTO's revival

decisions “to the class to which the [plaintiff] belongs” – those individuals or

entities sued for infringement (*i.e.*, putative third-party infringers). And as the

*Block* Court made clear, one analyzes the question of whether Congress intended to

foreclose judicial review of a given agency action through “inferences of intent

drawn from the statutory scheme *as a whole.*” *Block*, 467 U.S. at 349 (emphasis

added). One need not identify an express congressional statement precluding

review; instead, even where such “congressional intent is ‘fairly discernible’ in the

detail of the legislative scheme, APA review is not available.” *Id.* at 351.

**A. This Court in *Aristocrat* Held that Congress Did Not Intend For A Putative Third-Party Infringer to Shield Itself From Infringement Liability by Challenging the USPTO's Revival Decisions**

Here, the decision of this Court that allegedly “required” plaintiff to file the

instant APA action, A0030-0031 ¶24 (citing *Aristocrat Techs. Australia Pty Ltd. v. Int'l Game Tech.*, 543 F.3d 657 (Fed. Cir. 2008)), mandates the exact opposite conclusion than the District Court reached – that Congress intended to preclude judicial review of USPTO revival decisions at the behest of putative third-party infringers. Given its identity with the issue presented in this appeal, it is more than passing strange that Exela's opening brief eschews any meaningful analysis of this Court's opinion in *Aristocrat*, and discusses the same in a single, merely cursory, paragraph.

*Aristocrat* was an action in which a third-party facing infringement liability presented the very same argument that Exela raised in the District Court – *i.e.*, that the USPTO utilized the incorrect standard in reviving the international patent application that ultimately matured into the patent-in-suit – and sought to have the Court review the USPTO's revival order. *See Aristocrat*, 543 F.3d at 659-60. The district court in *Aristocrat* held that a putative infringer could assert that the USPTO had improperly revived the patent-in-suit, and that it could review the propriety of the USPTO's decision. *See, e.g., Aristocrat Techs. Australia Pty Ltd. v. Int'l Game Tech.*, 491 F. Supp. 2d 916, 930-31 (N.D. Cal. 2007), *rev'd*, 543 F.3d 637 (Fed. Cir. 2008).

This Court reversed through a detailed analysis of 35 U.S.C. § 282 – the

provision of the Patent Act through which Congress enumerated those remedies that individuals and entities, like Exela, would possess when faced with potential infringement liability. *See* 35 U.S.C. § 282. But in holding that a putative infringer was not entitled to argue that the USPTO improperly revived a patent in defending against liability, this Court did not simply rest – as Exela suggests here, *Brief*, at 55 – upon § 282. To the contrary, this Court held that “Congress made it clear in various provisions of” the Patent Act generally “when it intended to create a defense of invalidity or noninfringement,” but had failed to evince any such intent in the statutory provisions related to revival. *Aristocrat*, 543 F.3d at 662. And this Court also recognized – as the Supreme Court in *Block* held relevant to application of § 701(a)(1) – that the “objectives” of the Patent Act would be harmed by allowing putative infringers to obtain judicial review of the USPTO’s revival decisions:

If any prosecution irregularity or procedural lapse, however minor, became grist for a later assertion of invalidity, accused infringers would inundate the courts with arguments relating to every minor transgression they could comb from the file wrapper. This deluge would only detract focus from the important legal issues to be resolved – primarily, infringement and invalidity.

*Id.* at 663.

But that is *exactly* what Exela did here – “comb” through the file wrapper for the ’218 patent to uncover and ultimately assert any “prosecution irregularity”

it could find in an attempt to avoid liability. Exela has clearly conceded that the *only* reason that it filed the instant civil action is the existence of the pending infringement action against it in the District of Delaware. *See, e.g., Brief*, at 2 (“But for the PTO’s improper revival decision that enabled the issuance of the patent, Exela would not have been subjected to the expense of defending against a claim of infringing the revived patent.”). Although Congress articulated several grounds through the Patent Act on which an entity such as plaintiff could attempt to avoid this injury – including certain USPTO errors (*i.e.*, patent invalidity) – the USPTO’s purported error in reviving an expired international patent application through an improper standard is not among them. *See Aristocrat*, 543 F.3d at 662-63; *see also id.* at 633 (acknowledging that no provision of the Patent Act provides any “signal[] that Congress has given in other circumstances to indicate that these sections provide a defense to an accused infringer”).

As this Court has held, through words directly applicable here, “[t]he structure of the Patent Act indicates that Congress included only the *remedies provided therein* to ensure that the statutory objectives would be realized.” *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920, 938 (Fed. Cir. 1991) (emphasis added). Put simply, Exela asks this Court to allow it – a third-party competitor – “to collaterally attack issued patents through suits under the APA,” something that

this Court held “would destroy the Patent Act’s careful framework for judicial review at the behest of particular persons through particular processes.” *Pregis*, 700 F.3d at 1359.

Exela thus asks this Court to hold that Congress clearly intended to preclude a putative infringer from obtaining judicial review of the USPTO’s revival order as a defense to liability in the infringement action itself, but nonetheless wanted the same party to be able to file a separate civil action against the USPTO under the APA to obtain the very same review.<sup>15</sup> *Brief*, at 55 (arguing that “*Aristocrat* held that ‘improper revival’ is not a defense under [] § 282,” “but left undecided whether one could bring a direct APA action challenging” the very same decision). To both the District Court and Exela, this Court’s decision in *Aristocrat* was merely an exercise in promoting efficiency in infringement litigation (*i.e.*, that insertion of a “improper revival” defense would distract from other invalidity issues), and had little to do with Congress’s intent with respect to those matters that could defeat infringement liability more generally.<sup>16</sup> But by resting its position on

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<sup>15</sup>To its credit, Exela freely admits in its complaint that it brought the action *only* to obtain the very type of review that this Court’s decision in *Aristocrat* prevents it from securing in the underlying infringement action. A0030-0031 ¶24.

<sup>16</sup>Other than a conclusory phrase to the effect that “the procedural posture of the present case is more than a distinction in pleading formalities,” A0014, the District Court did explain how inserting a defense of “improper revival” into an infringement action causes untold confusion, when the filing of a separate action –

the slender reed of the specific civil action in which a putative third-party infringer raises its argument, and ignoring the obvious identity between the issue, class (*i.e.*, third-party infringers), and context that this Court confronted in *Aristocrat*, Exela essentially asks this Court to require an *express* congressional statement that its elimination of “improper revival” as a defense to infringement liability was *also* intended to preclude APA review of the very same decision. As the Supreme Court made clear in *Block*, and Exela concedes here, *Brief*, at 51, however, such an express provision is unnecessary to cause APA preclusion under § 701(a)(1). *See Block*, 467 U.S. at 345; *see also Pregis*, 700 F.3d at 1358 (“A statute need not explicitly state that judicial review is unavailable for preclusion to be found.”).

Exela’s position requires this Court to ignore the deliberate choices Congress made through the Patent Act concerning those “remedies,” *see Animal Legal*, 932 F.2d at 938, available to an entity facing infringement liability and to turn its decision in *Aristocrat* into a vapid pleading exercise. Indeed, acceptance of Exela’s position would pragmatically relegate *Aristocrat* – and its conclusions regarding Congress’s intent in this very context – to the jurisprudential scrapheap of history, as those facing infringement liability will simply flock to file new and

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involving (at least) the same litigants *and* the USPTO, and potentially in the very same court – is not a similar distraction from the “metes and bounds” of the subject patent.

separate civil actions against the USPTO seeking review of exactly the same decision. *See Aristocrat*, 543 F.3d at 663 (holding that judicial review of revival orders would lead to a “deluge” of such claims). As the Supreme Court has long held, “[i]t would require the suspension of disbelief to ascribe to Congress the design to allow its careful and thorough remedial scheme, to be circumvented by artful pleading.” *Brown v. GSA*, 425 U.S. 820, 833 (1976); *see Block v. North Dakota*, 461 U.S. 273, 285-86 (1983) (holding that litigants may not utilize the general judicial review provisions of the APA in order to avoid the limitations inherent in other remedies); *Am. Air Par. For. Co. v. United States*, 718 F.2d 1546, 1550 (Fed. Cir. 1983) (rejecting notion that “a litigant would be able to change the entire statutory scheme Congress has established” “[b]y artful pleading alone”). Exela cannot circumvent the Patent Act’s limitations on infringement defenses with the mere stroke of a pen, by including its “improper revival” argument in a new civil “complaint,” instead of an “answer” to an infringement action.

**B. The *Ex Parte* Nature of USPTO Revival Proceedings Under the Patent Act Provides Further Evidence of Congressional Intent to Preclude APA Review**

There are, however, other aspects of the Patent Act – not discussed in *Aristocrat*, and ignored by both the District Court and Exela alike – that also render Congress’ intent to preclude APA review “fairly discernible.” In particular, the

Supreme Court in *Block* placed significant weight on the fact that the parties seeking judicial review were not entitled to participate in the underlying administrative process that resulted in the challenged final agency action:

Nowhere in the Act, however, is there an express provision for participation by consumers in any proceeding. In a complex scheme of this type, the omission of such a provision is sufficient reason to believe that Congress intended to foreclose consumer participation in the regulatory process.

*Block*, 467 U.S. at 347. The Patent Act shares these qualities, among others found in the statute as a whole.

As stated earlier, courts have routinely recognized that the Patent Act renders administrative proceedings with respect to patents *ex parte* in nature – between the patent owner and the agency. The Patent Act thus generally provides for no involvement by putative third-parties – including, *inter alia*, those accused of infringement – in the administrative process through which issues related to a patent application is reviewed and decided. *See Hitachi Metals, Ltd. v. Quigg*, 776 F. Supp. 3, 8 (D.D.C. 1991) (noting the *ex parte* nature of patent prosecution). And Congress has shown that when it wants to involve third parties in the administrative review of patent issues, it knows how to do so. Congress has specifically provided that third parties are entitled to bring certain prior art references to the USPTO’s attention that might be relevant to a given patent, *see* 35

U.S.C. § 301, and may petition the agency either to undertake *ex parte* reexamination, *see id.* § 302, or to participate in *inter partes* or post grant review. *See id.* §§ 311; 321. Each of the instances in which Congress has expressed its desire to involve third parties in the administrative process relates to a particularized issue – the review of an issued patent on substantive patentability grounds. By contrast, Congress has not chosen to authorize involvement on the part of third parties in the USPTO’s administrative review of other issues, including the revival of international patent applications. And much like the statutory scheme in *Block*, in the face of specific authorization for participation in other contexts, “the omission of such a provision is sufficient reason to believe that Congress” intended to preclude Exela’s instant attempt to secure APA review. *Block*, 467 U.S. at 347.<sup>17</sup>

Courts have so held in analogous circumstances. In particular, in *Syntex*,

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<sup>17</sup>If the USPTO were required to entertain third party arguments about such matters, accused infringers “would inundate [the USPTO] with arguments relating to every minor transgression they could comb from the file wrapper” in an attempt to invalidate a given patent, something that would certainly distract the agency from other important issues. *Aristocrat*, 543 F.3d at 663. And of course, consistent with the position articulated above, if Congress did not desire putative infringers to obtain judicial review of the USPTO’s revival orders in an infringement action, it stands to reason that the legislature did not want those same third parties flocking to the USPTO to obtain the same relief.

this Court held – in the context of § 701(a)(1) – that “[t]he creation of a right or remedy in a third party to challenge a result favorable to a patent owner after *ex parte* prosecution would be unprecedented,” and refused to allow the third party resort to the APA. *Syntex (U.S.A.), Inc. v. USPTO*, 882 F.2d 1570, 1574-75 (Fed. Cir. 1989). And in *Hallmark Cards*, a third party sought APA review of the USPTO’s decision to issue a “certificate of correction,” 35 U.S.C. § 255, with respect to an already-issued patent. *Hallmark Cards v. Lehman*, 959 F. Supp. 539, 541-42 (D.D.C. 1997). After noting that administrative proceedings with respect to a patent owner’s request for a certificate of correction – just like the *ex parte* reexamination proceedings at issue in *Syntex* – were completely *ex parte*, the district court held “that Congress did not intend that third parties have the right to judicial review of Certificates of Correction issued by the PTO.” *Id.* at 544. Moreover, the district court in *Hallmark* held that the type of administrative action at issue was pertinent to whether Congress had precluded judicial review:

[I]t would strain credulity to conclude that Congress did not provide for judicial review by third parties of PTO decisions when the PTO conducts a thorough and comprehensive review of a patent in reissue and reexamination proceedings, but intended that third parties have the right to judicial review when the PTO issues Certificates of Correction, which involves a far less intrusive examination of a patent for minor, typographical, and clerical errors.

*Id.* at 543.

As provided earlier, administrative proceedings with respect to the revival of abandoned international patent applications are of a similar ilk, as neither the Patent Act nor the USPTO’s implementing regulations provide for “any participation by third parties.” *Id.* at 544. And as this Court held in *Aristocrat*, the type of administrative action at issue here – decisions regarding the revival of an expired patent – are exactly the type of “procedural minutiae” that are far divorced from the analytically-laden determinations that the USPTO undertakes in the substantive examination context. *See Aristocrat*, 543 F.3d at 663; *see also Hallmark Cards*, 959 F. Supp. at 543.<sup>18</sup>

<sup>18</sup>Exela repeatedly argues that preclusion of its ability to seek APA review here would end any judicial review of the USPTO’s revival standards. This is simply not the case. To be sure, this Court has held that “[t]here is a ‘strong presumption’ that Congress did not intend to prohibit all judicial review of a type of agency action.” *Pregis*, 700 F.3d at 1358 (quoting *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 672 (1986)). But the USPTO here only seeks – and the Patent Act only supports – preclusion of judicial review at the behest of putative third-party infringers, not judicial review of revival decisions by *anyone*. Indeed, there can be little doubt that a patent applicant whose *own* revival petition is *denied* by the USPTO would be entitled to APA review of that denial. *Cf.* *Burandt v. Dudas*, 528 F.3d 1329 (Fed. Cir. 2008) (exercising APA review over denial of petition to reinstate expired patent). And the mere fact that the particular standard at issue here favors applicants is not of moment, as the Supreme Court’s preclusion jurisprudence does not turn on the merits of the agency’s position, or some sense of the probability that others would exercise their right of judicial

## CONCLUSION

For the foregoing reasons, this Court should affirm the District Court's dismissal of Exela's complaint.

Respectfully submitted,

DANA J. BOENTE  
ACTING UNITED STATES ATTORNEY

By:                     /s/                      
DENNIS C. BARGHAAN, JR.  
Assistant U.S. Attorney  
2100 Jamieson Avenue  
Alexandria, Virginia 22314  
Telephone: (703) 299-3891  
Fax: (703) 299-3983  
Email: [dennis.barghaan@usdoj.gov](mailto:dennis.barghaan@usdoj.gov)

DATE: September 27, 2013

ATTORNEYS FOR DEFENDANT-  
APPELLEE

OF COUNSEL: Sydney Johnson  
Jamie Simpson  
Associate Solicitors  
United States Patent & Trademark Office

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review.

### **CERTIFICATE OF SERVICE**

I hereby certify that on September 27, 2013, I electronically filed the foregoing Appeal Brief of Defendant-Appellee, Teresa Stanek Rea, Acting Director, United States Patent & Trademark Office, with the Clerk of the United States Court of Appeals for the Federal Circuit using the CM/ECF System, which will send notice of such filing to all registered CM/ECF users.

\_\_\_\_\_/s/\_\_\_\_\_  
Dennis C. Barghaan, Jr.

## **CERTIFICATE OF COMPLIANCE**

I hereby certify, pursuant to Federal Rule of Appellate Procedure 32(a)(7)(B) and the Rules of this Court, that the foregoing brief has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman 14-point font, and contains 11,215 words (excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii) and by Federal Circuit Rule 32(b)).

\_\_\_\_\_/s/\_\_\_\_\_  
Dennis C. Barghaan, Jr.